GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:483
ANSWERED ON:27.07.2005
NORMS FOR CLINICAL TRIALS
Hasan Chaudhary Munawwar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that a large number of applications for clinical trial for GEAC approval are pending for want of DCGI`s comments;

(b) if so, the details of clinical trial applications pending with the GEAC; and

(c) the norms for granting approval for such clinical trials?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a): No applications for clinical trials are pending with GEAC for approval for want of DCG(I)`s comments.

(b)&(c): The GEAC takes a view on the request for clinical trials of recombinant Pharma products based on the pre-clinical study data and recommendation of Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology. DCG(I) is also a member of the GEAC and specific comments of DCG(I) are communicated in the GEAC meetings. Approval for clinical trial under Drugs and Cosmetics Rules are accorded as per norms stipulated under Schedule Y. Before initiation of trial, Ethics Committee approval of concerned Medical Institution is necessary.